
Examiner's Proposed Amendment

Draft

1. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicants, an amendment may be filed as provided by 37 C.F.R. §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview on XX August 2008 with Ms. Belinda M. Lew, Applicants' Representative.

In the Title:

Please change the current title with:

Composition for Treating Vascular Diseases Characterized by Nitric Oxide

Insufficiency

In the Abstract

Please change the current Abstract with following Abstract:

The present invention provides a composition comprising an antioxidant, and at least one of isosorbide dinitrate and isosorbide mononitrate in therapeutically effective dosage of each of the aforementioned compounds to treat cardiovascular diseases caused by nitric oxide (NO) insufficiency. The antioxidant is a hydralazine compound.

In the Claims:

1. (Currently amended) A sustained release oral formulation comprising biodegradable microparticles and/or nanoparticles having dispersed therein a therapeutically effective amount of at least one antioxidant and at least one of the isosorbide dinitrate and isosorbide mononitrate, wherein the isosorbide dinitrate is present in an amount [[of]] to deliver about 30 milligrams per day to about 160 milligrams per day and/ or the

isosorbide mononitrate is present in an amount to deliver about 5 milligrams per day to about 120 milligrams per day.

8. ((Currently amended) The sustained release oral formulation of claim 7, wherein the hydralazine hydrochloride is present in an amount ~~[[of]]~~ to deliver about 30 milligrams to about 400 milligrams per day.

9. ((Currently amended) The sustained release oral formulation of claim 8, wherein the hydralazine hydrochloride is present in an amount ~~[[of]]~~ to deliver about 50 milligrams to about 300 milligrams per day.

12 (Canceled)

13. (Currently amended) The sustained release oral formulation of claim ~~[[12]]~~ 1, wherein the isosorbide mononitrate is present in an amount ~~[[of]]~~ to deliver about 15 milligrams per day to about 100 milligrams per day.

18. (Currently amended) The sustained release oral formulation of claim 1, comprising ~~a therapeutically effective amount of~~ hydralazine hydrochloride as the antioxidant and isosorbide dinitrate.

19. (Currently amended) The sustained release oral formulation of claim 1, comprising ~~a therapeutically effective amount of~~ hydralazine hydrochloride as the antioxidant and isosorbide mononitrate.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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